UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,704	03/07/2002	Joseph Cohen	B45187	1683

20462 7590 08/29/2003

SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER	
MINNIFIELD, NITA M	
ART UNIT	**PAPER NUMBER**
1645	14

DATE MAILED: 08/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/018,704	Applicant(s) COHEN ET AL.	
	Examiner N. M. Minnifield	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 13-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 13-24 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) 1 Sheets
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicants' preliminary amendment filed December 13, 2001 is acknowledged and has been entered. Claims 1-12 have been canceled. New claims 13-24 have been added and are now pending in the present application.

2. The disclosure is objected to because of the following informalities: what does "G*" in WD1004 mean? At page 7, line 18, does Applicant intend "vaccine does" or "vaccine dose"? Appropriate correction is required.

Sequence Requirements

3. This application contains sequence disclosures (see page 6) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules is required in response to this office action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with ***both*** these requirements in the time period set forth in this office action will be held non-responsive.

4. Claims 14, 15, 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 14 and 15 are indefinite because they contain the abbreviations "RTS", "RTS*" and "TRAP". Full terminology should be in each instance in the claims without the additional use of redundant abbreviations in parentheses or otherwise. Correction is required. Claim 24 is vague and indefinite in the recitation of "suitable time"; how much time is "suitable time"? What are the metes and bounds of "suitable time"? Claims 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. With regard to claim 23, what are the components of the composition such that one of skill in the art would know that the method steps had achieved the claimed composition. The method also needs a final product step. With regard to claim 24, to whom is this being administered? The claim needs to recite "administering to a patient an effective...".

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 13, 17-21, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Caulfield WO 98/52962 or Jones et al 1999, Vaccine, 17:3065-3071.

The claims are directed to a composition comprising a malaria antigen and an immunostimulatory CpG oligonucleotide, as well as methods of producing the composition and using said composition in a method for prevention or amelioration of plasmodium infection in a patient.

Caulfield discloses a composition comprising a oligonucleotide adjuvant and antigen and methods of vaccination using the composition (abstract; p. 6; p. 11; claims). Caulfield discloses an oligonucleotide having the CpG motif (p. 5). Caulfield discloses that the antigen can be antigens from *Plasmodium* (i.e. malarial antigens) (see p. 7). Caulfield discloses that the antigen and adjuvant are administered closely in time, e.g. the adjuvant is administered within from about one minute to within about one day before or after the antigen is administered (p. 8).

Jones et al discloses compositions comprising malarial antigens and synthetic oligonucleotides containing CpG motif as adjuvant (abstract). Jones et al discloses that these oligonucleotides are based on immunostimulatory bacterial DNA sequences (abstract). Jones et al discloses methods of preparing the

composition as well as methods of administering the composition to a animal (materials and methods, p. 3066-67).

The prior art anticipates the claimed invention. The products disclosed in the prior art reference appears to be the same or obvious or analogous variants of the products claimed by Applicants because they appear to possess the same or similar elements or functional characteristics. The prior art is believed to inherently possess properties, which anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicants' products and methods and the products and methods of the prior art, the burden is on applicant to show a novel or unobvious differences between the claimed products and methods and the products and methods of the prior art (i.e., that the products and methods of the prior art does not possess the same material structural and functional characteristics of the claimed products and methods). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

8. Claims 13-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Friede et al 6558670.

Friede et al discloses a composition comprising a immunostimulatory oligonucleotides (i.e. CpG), saponin and an antigen (abstract; col. 9; claims). Friede et al discloses that the antigen can be from *P. falciparum* (i.e. malarial antigen) and that the composition may comprise combinations of more than one immunostimulatory oligonucleotide (cols. 5-6). Friede et al discloses that the vaccines "of the present invention further comprise antigens from parasites that cause Malaria. For example, preferred antigens from *Plasmodia falciparum*

include RTS,S and TRAP." (see col. 7). The prior art also sets forth methods of preparing the composition as well as methods of administering the composition to prevent or ameliorate *Plasmodium* infections in a patient (cols. 3, 8, 10).

The prior art anticipates the claimed invention. The products disclosed in the prior art reference appears to be the same or obvious or analogous variants of the products claimed by Applicants because they appear to possess the same or similar elements or functional characteristics. The prior art is believed to inherently possess properties, which anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicants' products and methods and the products and methods of the prior art, the burden is on applicant to show a novel or unobvious differences between the claimed products and methods and the products and methods of the prior art (i.e., that the products and methods of the prior art does not possess the same material structural and functional characteristics of the claimed products and methods). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

9. Claims 13 and 16-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Davis et al 6406705, Krieg et al 6207646, or Raz et al 6589940.

Davis et al discloses compositions comprising synergistic adjuvants (CpG and non-nucleic acid adjuvant) and antigen (abstract). The antigen can be a parasite antigen (i.e. malarial antigen) (see col. 2; col. 16). The non-nucleic acid adjuvant can be saponins or MPL (col. 4; col. 14). Davis et al discloses that the oligonucleotide size can be 8 to 100 nucleotides, preferably 8 to 40 nucleotides

(col. 4; col. 11). The prior art discloses methods of preparing the composition and administering the composition.

Krieg et al discloses compositions comprising a CpG adjuvant and antigen (abstract). The antigen can be a parasite antigen (i.e. malarial antigen) (see col. 11; col. 16). The non-nucleic acid adjuvant can be conventional adjuvants such as alum (col. 33). Krieg et al discloses that the oligonucleotide size can be 8 to 40 nucleotides (col. 6; col. 11). The prior art discloses methods of preparing the composition and administering the composition (claims; col. 34). Krieg et al discloses that the compositions can be used to treat, prevent, or ameliorate and immune system deficiency (i.e. parasitic infection) (see col. 6).

Raz et al discloses compositions comprising immunostimulatory oligonucleotides, CpG, and antigens (abstract). The antigen can be a parasite antigen (i.e. malarial antigen) (see col. 5; col. 16). The composition can comprise additional adjuvants (col. 6; col. 13-16). Raz et al discloses that the oligonucleotide size can be 6 to more than 20 nucleotides (col. 10). The prior art discloses methods of preparing the composition and administering the composition (col. 12).

The prior art anticipates the claimed invention. The products disclosed in the prior art reference appears to be the same or obvious or analogous variants of the products claimed by Applicants because they appear to possess the same or similar elements or functional characteristics. The prior art is believed to inherently possess properties, which anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicants' products and methods and the products and methods of the prior art, the burden is on applicant to show a novel or unobvious differences between the

claimed products and methods and the products and methods of the prior art (i.e., that the products and methods of the prior art does not possess the same material structural and functional characteristics of the claimed products and methods). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

10. No claims are allowed.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
8/21/03